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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,641	04/01/2005	Makoto Asakawa		6517
28213 7590 01/16/2007 DLA PIPER US LLP 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133			EXAMINER GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/762,641

Applicant(s)

ASAKAWA ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/13/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **Detailed Action**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/06 has been entered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a method of transferring a foreign gene from a first cell to a second cell through contact infiltration, comprising: inoculating the first cell but not the second cell with a ribonucleoprotein comprising an RNA of a non-segmented (-)RNA virus, wherein the ribonucleoprotein has autonomous replication ability, and the RNA comprises a foreign gene, and the RNA lacks a gene encoding Matrix (M) protein or comprises an inactivated gene encoding M protein; allowing the first cell to contact the

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second cell; and **detecting the presence of the foreign gene in the second cell** (emphasis added). Applicants indicate that support for the highlighted limitation can be found throughout the specification and specifically at paragraphs [0012] and [0013]. However, an examination of the application, as filed, does not support the instantly claimed limitation. Nowhere in the application as filed, does applicant literally recite detecting the presence of the foreign gene transferred to the second cell as a result of contact infiltration from the first cell. Additionally, nowhere in the instant application does applicant provide the protocols necessary for the skilled artisan to differentiate the second cell from the first and specifically detect the presence of the foreign gene in the second cell. This is a NEW MATTER rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai et al. in view of Zhang et al. or Nabel et al.

Applicants claim a method of transferring a foreign gene from a first cell to a second cell through contact infiltration, comprising: inoculating the first cell but not the second cell with a ribonucleoprotein comprising an RNA of a non-segmented (-)RNA virus, wherein the ribonucleoprotein has autonomous replication ability, and the RNA comprises a foreign gene, and the RNA lacks a gene encoding Matrix (M) protein or comprises an inactivated gene encoding M protein; allowing the first cell to contact the second cell; and detecting the presence of the foreign gene in the second cell.

Nagai et al. (WO 97/16538, published 5/9/97, see also equivalent publication EP 0 864 645, see pages 5-10, Fig. 1 and Claims 5, 7-8, 12, 14-15, 47-49) teaches a method for transferring a foreign gene from a first cell to a second cell comprising contacting (or inoculating) a ribonucleoprotein complex comprising an RNA from Sendai virus into the first cell, allowing the second cell to contact the first cell, wherein the ribonucleoprotein has autonomous replicative ability and comprises a foreign gene and lacks a functional gene encoding the M protein. The complex can be inoculated into a host cell which can be from a mammal and can function *in vivo*. Nagai et al. does not specifically teach detecting the presence of the foreign gene in the second cell.

Zhang et al. (Biochem. Biophys. Res. Comm., 1996, Vol. 227, pp. 707-711, see whole article, particularly the Abstract, Fig. 2, pp. 707-708) recites the use of an

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enhanced GFP marker which allows detection of gene transfer in mammalian cells and Nabel et al. (US 5,733,543, issued 3/31/1998, see whole document, particularly column 12) recites use of methods such as Southern blotting to detect the presence of genes transferred to mammalian cells.

Nagai et al. teaches the essential features of the claimed invention with the exception of detecting the gene(s) transferred to the second cell by the inoculated first cell. The question therefore is whether it would have been obvious for the ordinary skilled artisan to monitor transfer of the gene(s) of interest to the second cell. The answer must be yes because the purpose of the protocols disclosed by Nagai et al. is the transfer genes to target cells and said skilled artisan would of course seek to determine whether the transfer had been successful. The next question would be whether protocols were available for monitoring transfer of genes from one cell to another. The answer, from a review of the prior art, is that many procedures were available for monitoring gene transfer in cellular systems (see for example the teachings of Zhang et al. and Nabel et al.).

The ordinary skilled artisan, in practicing the methodology of Nagai et al. on transferring a foreign gene from a first cell to a second cell through contact infiltration would have been motivated to detect the presence of the foreign gene in the second cell to determine whether the transfer had been successful as one could not automatically assume that successful transfer had occurred. Once the ordinary skilled artisan sought to detect the presence of the foreign gene in the second cell, he/she would have been able to select from numerous procedures for detecting gene transfer, for example the

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use of GFP (as a gene transfer marker) as recited by Zhang et al. or use of Southern blotting to detect the presence of the transferred DNA (as recited by Nabel et al.). It would have been obvious for the ordinary skilled artisan to detect the presence of the foreign gene in the second cell because this would confirm that the foreign gene was transferred successfully. The ordinary skilled artisan could use any of numerous gene transfer detection systems (i.e. GFP markers or Southern blotting, etc.) as recited by Zhang et al and Nabel et al. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Miscellaneous:

In Claim 18, gene is misspelled as "gejne".

Any rejections not repeated in this Office Action are withdrawn.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
January 7, 2007

  
DAVID GUZO  
PRIMARY EXAMINER